K102178

SEP 2 2010

510(K) Summary, K10

MHC Medical Products
100 Commerce Blvd
Loveland, OH 54140
Ph: 513 354-2694
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Contact person: John Edmiston
Date prepared: July 16, 2010

1. **Trade Name: Easy•Touch Insulin Syringe**
   Common Name: Insulin syringe
   Classification Name: Syringe, piston, product code FMF, Regulation: 880.5860
   Class of device: Class II.

2. **The legally marketed device to which we are claiming equivalence [807.92(a)(3)] : Feel-ject Insulin Syringe made by Feel Tech (Korea) K070917 and Easy•Touch Insulin Syringe, K091474, MHC Medical Products.**

3. **Description of device: The Easy•Touch insulin syringe consists of a calibrated hollow barrel which can contain the medication and the distal end of barrel is fixed with needle . The needle cannot be exchanged after assembling because needle is fixed in the barrel nozzle lumen. The plunger and gasket are the same shape as the conventional insulin syringes. The needle cap cover is intended to provide physical protection to the needle tube. The cap is color coded orange, same as equivalent insulin syringes. The syringes are available in 0.3 ml/cc, 0.5 ml/cc and 1 ml/cc sizes. They are supplied with a sterile fluid path, (EO), non-toxic, and non pyrogenic, for single use only, disposable. The devices operate on the principles of common piston syringes. This premarket notification is for additional needle gauges and lengths as compared to our previous submission, K091472.**

4. **Intended use: For the injection of U100 insulin.**

5. **Technological characteristics: The Easy•Touch Insulin Syringes and the predicate devices have identical technological characteristics and perform the same way as common piston syringes. These syringes are EO sterilized.**

6. **Performance: Bench tests were performed. Bench testing included biocompatibility, mechanical testing, sterility testing including EO residues. The tests demonstrated that the device is as safe, as effective, and performs in a substantially equivalent manner to the predicate device.**

Exhibit 6. Truthful and Accuracy Statement as required per 21CFR807.87(k).

I certify that, in my capacity as Vice-president of MHC Medical Products, I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.

John Edmiston
July 16, 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MHC Medical Products
C/O Mr. Daniel Kamm
Kamm & Associates
8870 Ravello Court
Naples, Florida 34114

SEP 2 2010

Re: K102178
Trade/Device Name: Easy-Touch Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 19, 2010
Received: August 13, 2010

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K102178

510(k) Number (if known):

Device Name: Easy•Touch Insulin Syringe

Indications For Use:

The Easy•Touch disposable sterile insulin syringes are intended for injection of U100 insulin only.

Prescription Use ____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

9/1/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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